DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 10,2014

Leaf Healthcare Incorporated
C/O Mr. Ronald S. Warren
Experien Group, Limited Liability Company
Senior Director – Regulatory Affairs
755 N Mathilda Avenue, Suite 100
Sunnyvale, CA 94085

Re: K141877
Trade/Device Name: Leaf Patient Monitoring System
Regulation Number: 21 CFR 880.2400
Regulation Name: Bed-Patient Monitor
Regulatory Class: I
Product Code: KMI
Dated: October 13, 2014
Received: October 14, 2014

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141877

Device Name
Leaf Patient Monitoring System

Indications for Use *(Describe)*

The Leaf Patient Monitoring System monitors the orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. The Leaf Patient Monitoring System provides alerts when patient orientation or activity deviates from parameters set by healthcare providers. The device is intended for use in medical, nursing and long-term care facilities, including independent living, assisted-living and rehabilitation facilities.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Notification K 141877

GENERAL INFORMATION

Applicant:

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Date Prepared: July 10, 2014

DEVICE INFORMATION

Trade/Proprietary Name:
Leaf Patient Monitoring System

Generic/Common Name:
Bed-patient monitor

Classification:
21 CFR§880.2400, Bed-patient monitor, Class I

Product Code:
KMI, Monitor, Bed Patient

PREDICATE DEVICE

- Centauri Medical, Inc. DynaSense System (K130752)

INDICATIONS FOR USE

The Leaf Patient Monitoring System monitors the orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. The Leaf Patient Monitoring System provides alerts when patient orientation or activity deviates from parameters set by healthcare providers. The device is intended for use in medical, nursing and long-term care facilities, including independent living, assisted-living and rehabilitation facilities.

PRODUCT DESCRIPTION

The Leaf Patient Monitoring System is a medical device designed for use in hospitals, nursing homes, or other patient care facilities to monitor and report body orientation and activity, as well as to provide visual alerts for orientations and activity levels that fall outside of thresholds set by healthcare providers. The use of the Leaf Patient Monitoring System provides for continuous monitoring of patient position and allows caregivers to easily identify patients that are in need of caregiver-assisted turns according to the institution's guidelines or protocols. The use of the Leaf Patient Monitoring System can increase compliance with the care facility's prescribed patient tuning schedule and thereby may aid in the prevention of pressure ulcers.

The Leaf Patient Monitoring System is comprised of Patient Sensors, Leaf Antennas, and USB RF Transceivers, Turn Management Software, and a User Interface that can be viewed on a monitoring station. Each Leaf Patient Sensor is associated with a single patient, such that the patient's orientation, movements, and other care parameters can be monitored.

TECHNOLOGICAL CHARACTERISTICS

The Leaf Patient Sensor is a small, disposable sensor that adheres to a patient's skin, much like a standard electrocardiogram (EKG) lead. Once the Leaf Patient Sensor is applied to a particular patient, it continuously monitors the patient's orientation and movements and communicates this data wirelessly (via the Leaf Antennas) to a monitoring station that is equipped with a USB RF Transceiver and the Leaf Turn Management Software. The Leaf Turn Management Software collects and records all data for the Patient Sensors. Data for all monitored patients is ultimately displayed on the Leaf User Interface. Through the Leaf User Interface, caregivers can associate Patient Sensors with specific patients and also set individualized care parameters.

Multiple Leaf Antennas are installed throughout a monitoring environment to ensure adequate wireless coverage for a given area, such as a hospital ward or nursing unit.

Compared to the predecessor Centauri DynaSense device, the Leaf Patient Monitoring System has been updated with several minor modifications. These include updated aesthetics of the user interface, minor changes to the display features for user convenience and related software updates. The adhesive used to apply the device to the patient is unchanged, but a non-adhesive frame has been added around the adhesive to facilitate device removal from the patient's skin.

LABELING

One contraindication from the predicate IFU pertaining to the use of the system's sensor in patients who have a pacemaker or an implantable cardioverter-defibrillator (ICD), has been removed. Leaf Healthcare determined the system's sensor may be safely used in this subpopulation of patients, when an appropriate warning statement is provided to the user. A warning statement has been added to the IFU in order to safely enable the use of the device in this subpopulation of patients.

SUBSTANTIAL EQUIVALENCE

Aside from minor semantic differences such as the product name change, the indications for use for the Leaf Patient Monitoring System are identical to the indications for use for the predicate DynaSense System. The Leaf Patient Monitoring System and the predicate DynaSense System have the same intended use. The minor differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Leaf Healthcare analyzed the removal of the contraindication and addition of the warning statement to enable use of the device in patients with a pacemaker/ICD, and determined that these modifications raise no new issues of safety or effectiveness. Thus, the Leaf Patient Monitoring System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the Leaf Patient Monitoring System to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary:

The nonclinical, bench testing included:

- System performance testing;
- Software verification;
- Electrical Safety and EMC.

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Leaf Patient Monitoring System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective nonclinical testing results demonstrate that the Leaf Patient Monitoring System does not raise new questions of safety or effectiveness for monitoring patient activity when compared to the predicate device.

CONCLUSION

The Leaf Patient Monitoring System and the predicate DynaSense System have the same intended use and similar technological characteristics. The minor differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Device safety and performance testing have demonstrated that the Leaf Patient Monitoring System performs as intended in its intended use environment, and support the device performs at least as safely and effectively as the predicate DynaSense System.

SUMMARY

The Leaf Patient Monitoring System is substantially equivalent to the predicate device.